

15010199

APR - 5 2001

1.4 Summary Statement

Premarket Notification 510 (K)

Manufacturer Address:	L.C.C. pjur group Germany Rudolph-Diesel-Strabe 13 Trier 54292 Germany
Contact:	D. Laros
Designated Agent:	Apparel Source Incorporated
Contact:	Richard Harris
Device Name:	Patient Lubricant
Brand name:	pjur Eros
Common Name:	Lubricant
Registration Number:	880.6375
Classification:	Class I
Product Code:	KMJ
Specialty Group	884
Type:	Traditional

Description: pjur Eros is designed to aid in the insertion of diagnostic devices, birth control devices and to ease the insertion of latex gloves, condoms, dams, female latex condoms and other latex devices. The latex safe formula is designed to better lubricate the body's orifices to facilitate the entry of such devices.

Performance Standards:

Latex Compatible (Article 1)

Non-Toxic (Article 2 + 3)

German Government Approved CE (Article 4)

Conclusion: Based upon findings in Articles 1-4 and that the product pjur Eros is substantially equivalent to *Aqua lube* (see 1.8 Substantial Equivalent), pjur Eros is safe for use as a medical device class I.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR - 5 2001

L.C.C. Pjur Group Germany  
c/o Mr. Richard Harris  
Apparel Source, Inc.  
65 Bank Street, Suite #9  
NEW YORK NY 10014

Re: K010199  
Pjur Eros Water Formulation  
Dated: December 15, 2000  
Received: January 22, 2001  
Regulatory Class: II  
21 CFR §884.5300/21 CFR §880.6375  
Procode: 85 HIS/80 MMS

Dear Mr. Harris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

K010199

1.6 Indications for Use Statement

Premarket Notification 510(k)

Applicant: A.S.I.

510(k) Number K010199

Device Name: Patient Lubricant

Indications for Use:

Formulated to give additional moisture wherever needed. Non-toxic and tasteless. Safe with condoms. Eros water formulation is not a contraceptive. Safe for daily use.

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Concurrence of CDRH, office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

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*David G. Regan*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K010199

~~Over-the-Counter Use~~ ✓